MEDDAC/DENTAC Regulation 40-11

Medical Services

Adverse Drug Reaction (ADR) Reporting Program

Headquarters
U.S. Army Medical Department Activity
Fort George G. Meade
2480 Llewellyn Avenue
Fort George G. Meade, MD 20755-5800
1 August 2002

Unclassified

SUMMARY of CHANGE

MEDDAC REG 40-11
Adverse Drug Reaction (ADR) Reporting Program

Specifically, this revision—

- Has been published in a new format that includes a cover and this "Summary of Change" page.
- Reformats the title page. The Contents section now includes the page numbers that the various chapters and paragraphs begin on.
- Removes the option of reporting adverse drug reactions by telephone (para 5c).

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Headquarters
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FOR THE COMMANDER:

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History. This is the fourth revision of the regulation, which was originally published on 15 April 1994.

Summary. The intent of the ADR Reporting Program is to identify and review adverse drug reactions in order to improve the safe and appropriate use of drugs.

Applicability. This regulation applies to Headquarters, U.S. Army Medical Department Activity, Fort George G. Meade (MEDDAC) and all of its outlying clinics, and to the U.S. Army Dental Activity, Fort George G. Meade (DENTAC).

Proponent. The proponent of this regulation is the Chief, Pharmacy Service.

Supplementation. Supplementation of this regulation by subordinate commanders and directors is prohibited.

Suggested improvements. Users of this publication are invited to send comments and suggested improvements by memorandum, directly to Commander, U.S. Army Medical Department Activity, ATTN: MCXR-PS, 2480 Llewellyn Ave., Fort George G. Meade, MD 20755-5800 or to the MEDDAC's Command Editor by fax to (301) 677-8088 or e-mail to john.schneider@na.amedd.army.mil.

Distribution. Distribution of this publication is by electronic medium only.

* This publication supersedes MEDDAC/DCC Reg 40-11, 11 August 1999.

Contents (Listed by paragraph and page number)

1. Purpose

This regulation establishes policy and procedures for the collection of data concerning ADRs. The program benefits all practitioners, especially those whose prescribing practices may have led to such reactions, as well as to patients who may be treated in the future with the involved drugs.

2. References

Related publications, prescribed forms and referenced forms are listed in appendix A.

3. Explanation of abbreviations and terms

Abbreviations and special terms used in this regulation are explained in the glossary.

4. Responsibilities

a. *The MEDDAC Commander and MEDDAC Executive Committee.* The MEDDAC Commander and MEDDAC Executive Committee are jointly responsible for overseeing the ADR Program, authorizing and supporting, as necessary, the actions of the Pharmacy and Therapeutic Committee (PTC).

b. *Commanders and directors of outlying clinics.* Commanders and directors of outlying clinics will report all ADRs to the Chief, Pharmacy Service.

c. *The Commander, DCC.* The Commander, DCC will report all ADRs occurring in dental treatment facilities at Fort Meade to the Chief, Pharmacy Service.

d. *The PTC.* The PTC will review ADR reports bimonthly. The committee will communicate all conclusions, recommendations and follow up evaluations to the Executive Committee.

e. *The Chief, Pharmacy Service.* The Chief, Pharmacy Service will review all ADR reports before forwarding them to the PTC, present the reports to the PTC for review, and submit, based upon professional judgement, all ADR reports to the Food and Drug Administration (FDA) that warrant further submission. For FDA reporting purposes, the FDA categorizes a reportable serious adverse event as one in which "the patient outcome is death, life-threatening, hospitalization, disability (significant, persistent or permanent), congenital anomaly or required intervention to prevent permanent impairment or damage.

f. *Attending physicians and dentists.* Attending physicians and dentists will submit ADR reports to the Chief, Pharmacy Service whenever an adverse drug reaction is noticed. (Reports from attending dentists will be submitted through the Commander, DCC. (See para 4*c* above.))

g. *Nursing Services and dental clinic personnel.* Nursing Services and dental clinic personnel will notify attending physicians and dentists of any unusual reactions to drug therapy that they become aware of. They will also notify the Chief, Pharmacy Service.

5. Procedure

a. Upon discovery of an ADR, the attending physician, dentist, or other healthcare provider who ordered the drug will be notified.

b. An entry of the ADR will be properly recorded in the patient's medical/dental record and the Composite Health Care System (CHCS) allergy profile.

c. All recognized or suspected ADRs will be reported to the Chief, Pharmacy Service on MEDDAC Form 492 (Adverse Drug Reaction Reporting Form) or through the CHCS computer system using mailgroup G.KADR.

d. The Chief, Pharmacy Service will review all ADR reports and present them to the PTC.

e. When deemed necessary by the PTC, the Chief, Pharmacy Service, the clinical pharmacist or prescribing provider, FDA Form 3500 (FDA MedWatch Form) will be submitted to the FDA. (Although anyone is authorized to submit FDA Form 3500 directly to the FDA, for the purpose of ensuring the Chief, Pharmacy at KACC is aware of the ADR, all MEDDAC personnel are requested to submit recognized or suspected ADRs to the Chief, Pharmacy Service at KACC in accordance with para c, above. The Chief, Pharmacy Service will then complete the FDA Form 3500, based on the submitted MEDDAC Form 492, and submit it to the FDA.)

Appendix A
References

Section I
Required Publications

This section contains no entries.

Section II
Related Publications

A related publication is merely an additional source of information. The user does not have to read it to understand this publication.

AR 40-3
Medical, Dental and Veterinary Care

AR 310-50
Authorized Abbreviations, Brevity Codes, and Acronyms

Section III
Prescribed Forms

MEDDAC Form 492
Adverse Drug Reaction Reporting Form. (Prescribed in para 5.)

Section IV
Referenced Forms

FDA Form 1639
Drug Experience Report

Glossary

Section I
Abbreviations

ADR
adverse drug reaction

CHCS
Composite Health Care System

DENTAC
U.S. Army Dental Activity, Fort George G. Meade

FDA
Food and Drug Administration

MEDDAC
U. S. Army Medical Department Activity, Fort George G. Meade

PTC
Pharmacy and Therapeutics Committee

Section II
Terms

Adverse drug reaction (ADR)

a. The American Society of Health-System Pharmacists defines a significant ADR as any unexpected, unintended, undesired or excessive response to a drug that causes any of the following conditions:

(1) Requires discontinuing the drug.
(2) Requires changing drug therapy.
(3) Requires modifying the dose.
(4) Necessitates admission to a hospital.
(5) Prolongs stay in a health care facility.
(6) Necessitates supportive treatment.
(7) Significantly complicates diagnosis.
(8) Negatively affects prognosis.
(9) Results in temporary or permanent harm, disability or death.

b. Consistent with this definition, an *allergic reaction* (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an *idiosyncratic reaction* (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs.